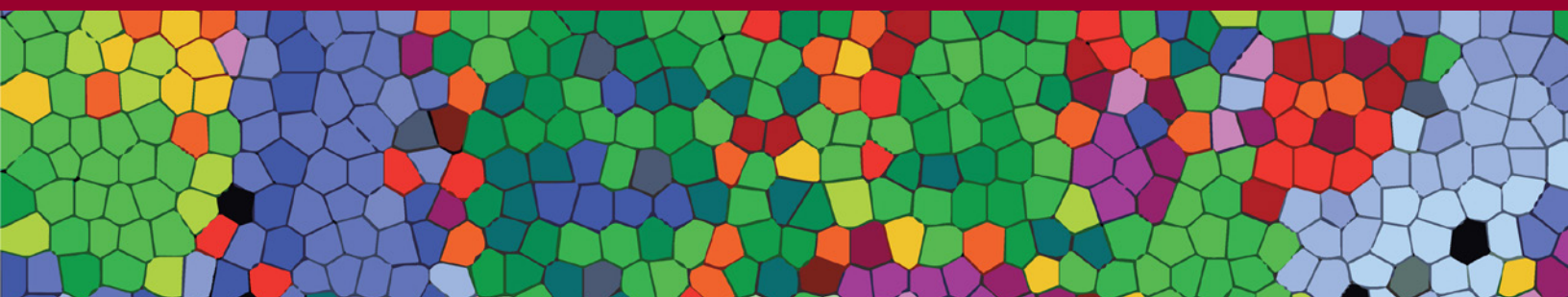


Beyond the Biopsy

Summary Report
September 2020



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Beyond the Biopsy Initiative

The Global Liver Institute (GLI) Beyond the Biopsy Initiative was developed to promote awareness and education about the use of non-invasive diagnostics as an alternative to biopsies. The Initiative also directs advocacy support to encourage greater adoption of non-invasive diagnostics by directly influencing legislative, regulatory, and coverage/reimbursement changes.

While COVID-19 has swept across the world, it is important to note that liver health patients are still facing procedures, a need for care, and are at a higher risk for COVID-19. GLI is committed to the safety and well being of patients and partners during the COVID-19 pandemic. For this reason, the 2020 Beyond the Biopsy Initiative was completely virtual, featuring a U.S.

radio media tour and virtual panel discussions to increase awareness about non-invasive diagnostics, the risks associated with biopsy, and the range of non-invasive options available to patients and providers for diagnosis. Throughout the month of September, the LIVE Beyond the Biopsy panel discussions featured Members of the United States Congress in addition to well known international, clinical, research, and patient experts in liver disease, NAFLD/NASH, diagnostics, and public health using the experience in Colorado, Massachusetts, and New York as jumping off points for discussion. The month-long initiative also included a comprehensive social media messaging campaign and MAT release which engaged tens of millions of users in the U.S. and worldwide.

Background

The benefits of liver biopsy were discovered as early as the 1880s and, in the absence of other diagnostic methods, liver biopsy gradually became referred to as the “gold standard” for liver assessment - a way for physicians to see the fat and degree of damage in a sample of liver cells. Today however, with global, pandemic-scale liver diseases, liver biopsy is not suitable for widespread use. It is time-consuming for the patient, a medical resource-intensive surgical procedure with documented risks, and its results are subject to sampling error (i.e., results reflect only the area of the liver actually biopsied), and subject to potentially over or underestimating liver damage. It is also an expensive procedure

and may require patients to take multiple days off from work, particularly if complications occur.

Recognizing the advances in non-invasive diagnostics, not only despite, but in some cases, accelerated by the pandemic, we brought experts together including liver health specialists, patients, and US Congressmen for conversations to raise awareness about the ways we can move away from biopsies and toward non-invasive diagnostics for liver diseases. It is time to move beyond the biopsy.



Beyond
the Biopsy

Key Numbers



1 National Radio Media Tour

1k Radio and Online Airings, 11.8M Cumulative Audience



2 Statements from Members of Congress



3 U.S. States targeted

Colorado, Massachusetts, New York



4 Beyond the Biopsy Educational Panels



988.8k #BeyondtheBiopsy impressions



246.7M Unique Visitors

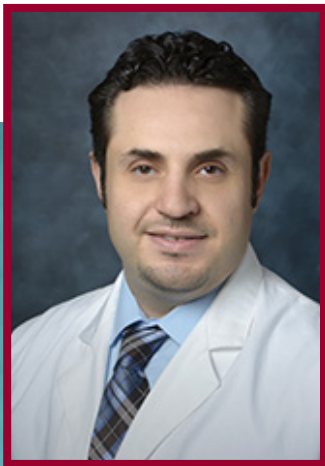
From 2.5K Placements of a MAT article

Beyond the Biopsy Radio Media Tour

A radio tour on Monday, August 31 of local, regional, and national radio shows featured GLI's President and CEO, Donna Cryer, JD, and Mazen Nouredin, MD - Director, Cedars-Sinai Fatty Liver Program

- 11,733,785 Cumulative Radio Airings
- 108,131 Online Audience
- 979 Audio News Release Airings

Visit globalliver.org/beyond for a digital sample of the Radio Media Tour



Mazen Nouredin, MD
Director, Cedars-Sinai
Fatty Liver Program,
Los Angeles, CA, USA



Donna Cryer, JD
President, and CEO
Global Liver Institute
Washington, DC, USA



Beyond the Biopsy GLI LIVE Series Overview

Beyond the Biopsy GLI LIVE: Colorado



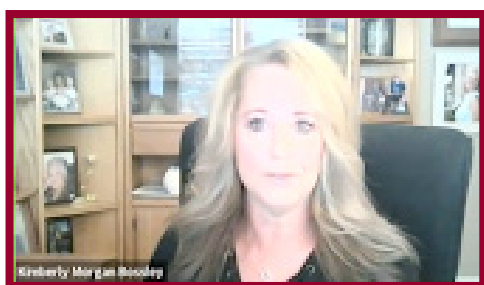
“We need to think differently to practice differently.”

US Representative Jason Crow



Introduction

US Representative **Jason Crow** (CO-6)



Guest

Kimberly Morgan Bossley
President, The Bonnie Morgan Foundation



Host

Donna Cryer, JD
President, and CEO, Global Liver Institute

See Appendix B for a full synopsis

Beyond the Biopsy GLI LIVE: Massachusetts



“Although it is the ‘gold standard,’ biopsy leaves a lot to be desired.”

Raymond Chung, MD, FAASLD



Host

Donna Cryer, JD
President, and CEO, Global Liver Institute



Guest

Scott Linscott
Liver Transplant Patient and Advocate



Guest

Mukesh Harisinghani, MD
Professor of Radiology, Harvard Medical School
Director of Abdominal MRI, Massachusetts
General Hospital



Guest

Raymond Chung, MD, FAASLD
Director of Hepatology and the Liver Center, Vice
Chief of Gastroenterology, Massachusetts General
Hospital; President-Elect - AASLD

See Appendix C for a full synopsis

Beyond the Biopsy GLI LIVE: New York



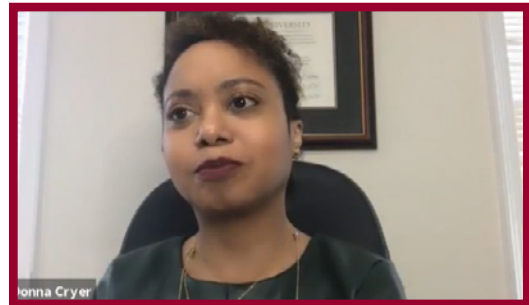
“Sometimes we forget that that patient represents a whole circle of other lives that are touched.”

Scott Friedman, MD



Special Message

US Representative **Adriano Espaillat** (NY-13)



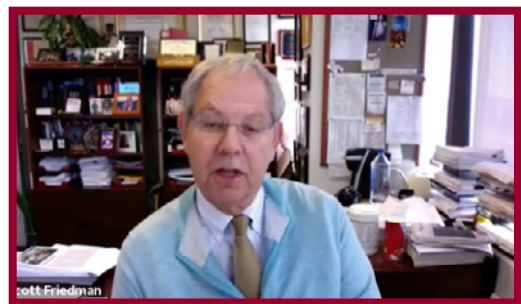
Host

Donna Cryer, JD
President, and CEO, Global Liver Institute



Guest

Gerard Marinaccio
Liver Transplant Patient and Advocate



Guest

Scott Friedman, MD
Dean for Therapeutic Discovery and Chief of the Division of Liver Diseases, Icahn School of Medicine at Mount Sinai

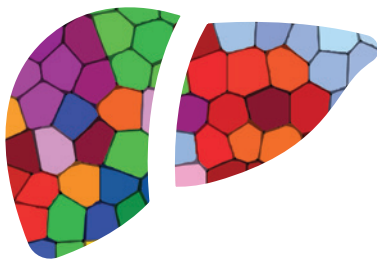
See Appendix D for a full synopsis

Beyond the Biopsy GLI LIVE: The Wrap-Up



“It has been a long journey that I hope to continue, certainly. But it has been populated from time to time by liver biopsies, which were in some cases painful, in all cases invasive, and something that has impassioned me to make sure we move beyond it.”

Donna Cryer, JD



See Appendix E for a full synopsis

Media Statistics

Radio Media Tour

A radio tour on Monday, August 31 of local, regional, and national radio shows featured GLI's President and CEO, Donna Cryer, JD, and Mazen Nouredin, MD - Director, Cedars-Sinai Fatty Liver Program

11,733,785

Cumulative Radio Airings

108,131

Online Audience

979

Audio News Release Airings

MAT Release

GLI wrote and distributed a MAT article, which appears as promoted content in both online and print publications.

2460

Mat Release Postings

246,694,681

Unique Visitors

See Appendix A to read the full MAT article



Social Media Campaign

Objectives

1. Educate about non-invasive diagnostics
2. Create awareness about the risks of biopsy
3. Highlight issues important to liver patients
4. Illustrate new research on non-invasive diagnostic technologies



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#BeyondTheBiopsy

Performance Across All Platforms

249
posts

1,080
engagements

113,023
reach

988,801
impressions

International Reach

On Twitter, users posted with the hashtag #BeyondtheBiopsy worldwide across cities such as:

- Mexico City, Mexico
- Amsterdam, Netherlands
- Zarate, Argentina
- London, United Kingdom
- Edinburgh, Scotland
- Abuja, Nigeria
- Brisbane, Australia
- Kolkata, India



In the majority of circumstances,
non-invasive diagnostics
(such as blood tests and imaging tests)
can be used to avoid liver biopsy

Talk to your doctor.













Educational Tiles

GLI Created custom graphics for sharing across social media platforms.

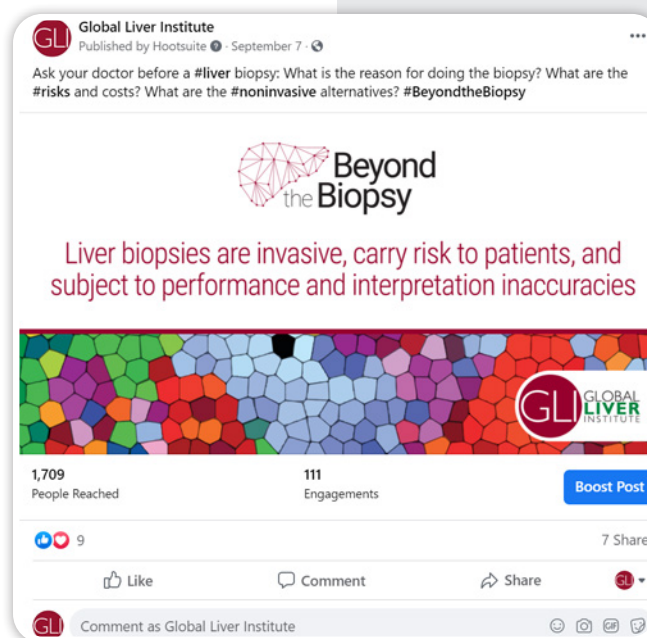
Influencers

Top users who posted with hashtag #BeyondTheBiopsy in September 2020 across Twitter, Facebook, and Instagram

USER	FOLLOWERS	AVG ENG
 GlobalLiverInstitute @globalliver Auth ✓	2,433	26
 Global Liver Institute @globalliver Auth ✓	2,793	23
 Global Liver Institute @globalliverinstitute Auth ✓	2,079	14
 Raquel Peck BR GB @raqpeck	2,054	10
 Mazen Nouredin, MD, MHSc @nouredinmd	2,271	8
 Livia Alimena LREUIT @liviaalimena	356	7
 Perspectum @perspectumgroup	1,045	5
 Tony Villiotti @tonyvilliotti	17	2
 Sarah says "mRNA vaccines are... @angryannabella	307	1
 Health Radio Online @healthproradio	1,235	0

Most Influential Facebook Post

1,709 people reached
111 engagements



Global Liver Institute
Published by Hootsuite · September 7 ·

Ask your doctor before a #liver biopsy: What is the reason for doing the biopsy? What are the #risks and costs? What are the #noninvasive alternatives? #BeyondtheBiopsy

Beyond the Biopsy

Liver biopsies are invasive, carry risk to patients, and subject to performance and interpretation inaccuracies

1,709 People Reached 111 Engagements [Boost Post](#)

9 7 Shares

Like Comment Share

Comment as Global Liver Institute

Educational Materials

Biopsy Basics

Liver biopsy has historically been associated with diagnosing liver disease and is still frequently used in clinical trials. Liver biopsy may be valuable but, increasingly in clinical practice, non-invasive diagnostics can be used. Liver biopsies are invasive, carry risk to patients, and subject to performance and interpretation inaccuracies.

In the majority of circumstances, non-invasive diagnostics (such as blood tests and imaging tests) can be used to avoid liver biopsy and provide more information than a biopsy through their ability to assess broader changes in the liver rather than only in the relatively small amount of liver tissue typically obtained from a liver biopsy.

Ask Your Doctor Before the Biopsy

- What is the reason for doing the biopsy?
- What are the noninvasive alternatives?
- What are the processes for minimizing pain and discomfort?
- How is the risk of bleeding minimized?
- How soon will I get the results?

Complications of Biopsy

Complications are rare, but can occur. Complications of biopsy include:

- Bleeding
- Pneumothorax
- Hemothorax
- Perforation of viscous organs
- Inadvertent biopsy of the kidney
- Bile peritonitis
- Infection (bacteremia, abscess, sepsis)
- Hemobilia
- Death

Alternatives to Biopsy

In some circumstances, a liver biopsy is extremely valuable, helpful, and perhaps even necessary, but in other circumstances non-invasive diagnostics can be used to avoid liver biopsy. These non-invasive alternatives potentially provide more information than biopsy, through their ability to assess changes throughout the liver, rather than only in the relatively small amount of liver tissue typically obtained from a liver biopsy.

From blood tests to imaging, alternatives to biopsy exist. Healthcare providers should increase the number of diagnoses and decrease the number of liver biopsies using non-invasive diagnostics.

What non-invasive diagnostics are there?

- Blood tests: Different tests on the blood to calculate the amount of fat in the liver. They can be imprecise and not reflect the true degree of liver fibrosis. Specific blood tests include AST to Platelet Ratio Index (APRI), Fibrosis-4 Test (FIB-4), Enhanced Liver Fibrosis (ELF), and FibroTest.
- Multiparametric Magnetic Resonance Imaging (LiverMultiScan): Imaging technology that uses MRI to measure liver fat, iron, fibrosis and inflammation in a scan of up to 15 minutes.
- Transient Elastography (Fibroscan): Imaging device that uses ultrasound to measure liver stiffness.
- Magnetic Resonance Elastography (MRE): Imaging technology that combines MRI with sound waves to create a visual map (elastogram) to measure liver stiffness.
- Shear Wave Elastography: Imaging technology that uses ultrasound to measure liver stiffness.

Ask your doctor which tests are appropriate in your case.

Going Beyond the Biopsy

Non-invasive alternatives are necessary to respond to the growing incidence of NAFLD, NASH, and other liver diseases. The symptoms of NASH are hard to recognize, as such, it remains under diagnosed. Newer non-invasive screening and diagnostic tools are now being used, offering a safer and more thorough examination of the liver.

Patient Voices

“The biopsy was very frightening. It’s degrading using bedpans, and horrendous lying motionless for hours afterwards. I have since had more biopsies, each one equally painful and traumatic - meaning time off from work for my husband or daughter.”

- Jenny, Liver transplant patient who has undergone multiple biopsies

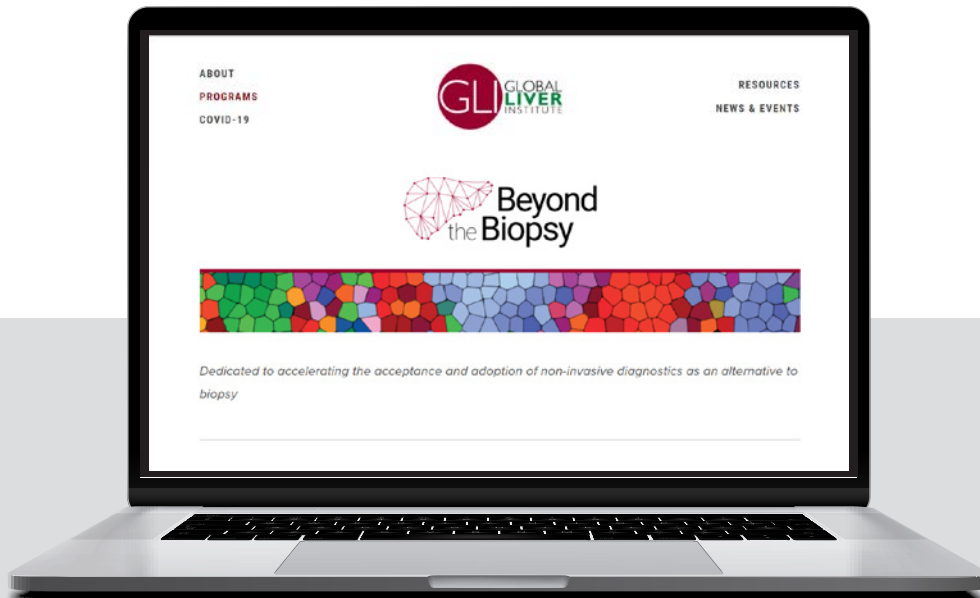
“I only found out my diagnosis, NASH, from my discharge papers. I found out what NASH was by looking it up on Google. I definitely would have benefited from point-of-care patient counseling.”

- Kimberly, NASH and liver transplant patient

Website

GLI's Beyond the Biopsy section of the website featured in-depth education about non-invasive diagnostics and shared patient stories about their experience with biopsy.

The website also provides access to recordings of the radio media tour and virtual panels. For more information, visit the GLI Beyond the Biopsy page at globalliver.org/beyond



Beyond the Biopsy Staff



Jeff McIntyre
NASH Program Director



Andrew Scott
Director of Policy



Carrie Gelula
Director of Communications



Jana Bernard
Social Media Director

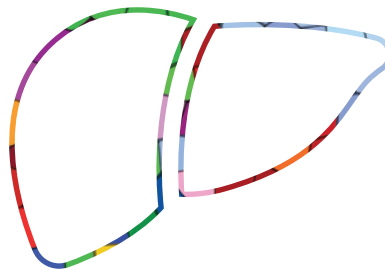


Marney O'Connor
NASH Program Intern



Ian Molloy
Operations Intern

We are grateful to the entire GLI team for their important contribution and support.



We look forward to the continuation of the Beyond the Biopsy Initiative throughout the year and into the future

For more information contact Beyond@globalliver.org



GLI Thanks Our 2020 Beyond the Biopsy Sponsors



Appendix A: MAT Release Article

HEALTH

Non-invasive Screening Finds Liver Disease Early

NewsUSA

(NU) - One quarter of the global population is estimated to have a liver disease called Nonalcoholic Fatty Liver Disease (NAFLD), a condition where the liver consists of 5 percent or more fat. Untreated, this disease can lead to the more severe Nonalcoholic Steatohepatitis which can result in cirrhosis, liver cancer, or liver transplant.

These liver diseases may become life-threatening without any noticeable symptoms, which is why screening is vital. For people who are at high risk, such as those living with obesity, pre-diabetes, or type 2 diabetes, talk to your doctor about your liver health and get screened as early as possible. In the past, the best way to diagnose liver disease was by performing a liver biopsy, a procedure where a small piece of the liver is removed using a long needle and then analyzed in a lab. Liver biopsies can be painful, risky, expensive, and unreliable. Complications can include bleeding, infection, accidental injury to a nearby organ, and even death. A typical liver biopsy can cost more than \$7,000. Additionally, a biopsy relies on using a tiny fraction of the liver, which means more than 30 percent of liver biopsy diagnoses may be wrong.

Fortunately, there are now al-



ternatives to biopsy. It is important for all healthcare providers and patients to understand that liver biopsy is not the only diagnostic option available. Some examples of non-invasive diagnostics include blood tests, ultrasound, and various different scans. Non-invasive diagnostics lead to fewer patient visits, quicker diagnosis, and are more cost-effective without the risks of surgery. Imaging tests can provide you and your doctor with a full picture of the liver, rather than just a small sample. If your doctor recommends a biopsy to screen for early liver disease, ask for non-invasive alternatives such as blood tests and imaging.

For more information about liver health and non-invasive screening for liver disease, visit GlobalLiver.org/Beyond.

Appendix B: Colorado Panel Synopsis

Introduction: US Representative Jason Crow (CO-6)

Guest: Kimberly Morgan Bossley (President, The Bonnie Morgan Foundation)

US Representative, Jason Crow (CO-6) Excerpt

Over the past few decades, liver diseases have risen to one of the leading causes of morbidity and mortality across the globe. These liver diseases are often driven by conditions such as obesity, type II diabetes, lifestyle practices, nutrition, and other factors. When it comes to diagnosing liver diseases, biopsies are a gold standard that can be scary and painful for patients. Chronic liver diseases are often underdiagnosed due to access to a biopsy and they are far more prevalent than what the data shows us.

In Colorado, this issue presents itself uniquely. Coloradans who have lost healthcare due to the COVID-19 pandemic or who live in rural areas of Colorado experience particular barriers to getting access to primary and specialized care. We need to focus on getting non-invasive diagnostics to more people such as blood tests and ultrasounds. These non-invasive diagnostics are a crucial part of diagnosing and treating diseases such as non-alcoholic fatty liver disease, non-alcoholic steatohepatitis, and other chronic liver conditions. Due to environment, genetics, concurrent conditions, and other factors, it is estimated that over 200,000 could have or be at risk for liver diseases.

Discussion Synopsis

Donna Cryer's Experience with Biopsies

In Donna's experience, the experience of getting a biopsy can be painful, long, and tiring. The traditional model consists of a long needle being injected between the rib cage where a piece of liver is extracted. From there, you are instructed to lay on your side for hours to prevent hemorrhage. Beyond the Biopsy was developed for a simple reason: we can do better than this.

Kimberly's Personal Experience and Inspiration

In 2005, Kimberly and her mother were both diagnosed with Hepatitis C. At the time, there were no options besides biopsy for diagnosis. So, they both underwent abdominal biopsies. After facing the loss of her mother in 2006, Kimberly tried to keep a positive outlook but eventually had to return for another biopsy in 2010. The second biopsy went in through the jugular vein to extract a piece of liver.

The Bonnie Morgan Foundation

In memory of her mother, Kimberly founded the Bonnie Morgan Foundation (BMF). The original vision was to provide financial help to patients with co-pays but a need for patient education was quickly realized. Patients are not given enough information at diagnosis so Kimberly redirected the Foundation to address that need. Every member of the Foundation is a patient, including one pediatric patient.

Pediatric Liver Diseases

When children get chronic liver diseases, they can be subject to biopsies. There is an urgency to push non-invasive diagnostics because there are still biopsies present in the pediatric setting even though other options exist. There are other ways to diagnose, including blood tests and taking detailed histories, that can be used in primary care settings. Whether it is a large hospital in the middle of a city or a doctor's office in a rural community, there should be a way to make these diagnostic technologies available and does not compromise patient safety and comfort.

“Patient to Patient Brainstorm”

Being a voice on social media is crucial in today's day and age. People actively seek out social media for answers to their questions about liver health. Utilizing this tool may be beneficial because no one used to talk about Hep C. Social media is a way for people to reach out while still remaining fairly anonymous in their day to day life and can be used for a new approach to patient advocacy.

The Concoction

Kimberly's provider, Dr. Everson, provided phenomenal care from drug treatment to bedside manner. An example of this was what Kimberly referred to as the “concoction”, also known as “colate” as part of the HepQuant SHUNT test. With this test, colate is administered both through an IV and orally, filters through the body, and then five timed blood samples are drawn over 90 minutes. The SHUNT test provides information on a patient's liver function and is a way to avoid a biopsy but still get the results desired for treatment.

The Need, Opportunity, and Value of Non-Invasive Diagnostics

The Global Liver Institute's aim with the Beyond the Biopsy Program to highlight the need, opportunity, and value of non-invasive diagnostics from a patient perspective. There are examples of complementary initiatives in the field such as the Friends of NIH's NIMBLE (Non-Invasive Biomarkers of Metabolic Liver Disease) and Europe's LITMUS (Liver Investigation: Testing Marker Utility in Steatohepatitis) programs, which also aim to make non-invasive diagnostics a new standard.

To showcase the work of many doctors and policymakers who are doing similar work, using the patient voice has never been more important in showing that the time is now for non-invasives. If the end of excessive and unnecessary biopsies is the lasting legacy of this program, that would be a true success.

When people ask, “why is this so important?,” the answer is not as simple as “I don't like needles,” it's about being able to see liver health at the level of priority it needs to be for the millions of people who need it. We need to think differently to practice differently and the patient voice is at the center of this conversation.

The Bonnie Morgan Foundation and Next Steps

Kimberly's Bonnie Morgan Foundation is available online during COVID and is providing Facebook events and other social media that are confidential and supportive for patients. These events serve as support groups with the Facebook group being anonymous because, although there is a need for a “face” of Hepatitis C, people don't always want to be that person. With BMF, they can feel safe and supported.

Appendix C: Massachusetts Panel Synopsis

Raymond Chung, MD, FAASLD - Director of Hepatology and the Liver Center, Vice Chief of Gastroenterology, Massachusetts General Hospital; President-Elect - AASLD

Mukesh Harisinghani, MD - Professor of Radiology, Harvard Medical School Director of Abdominal MRI, Massachusetts General Hospital

Scott Linscott - Liver Transplant Patient and Advocate

Discussion Synopsis

Why do we do liver biopsies?

Biopsies have been considered a “gold standard” and seen as the best we have for determining the origins and severity of liver diseases. It can help determine the stage of NAFLD in a liver and the level of fibrosis. However, there are a significant number of downsides to biopsies. Possible risks include hemorrhage, damage to the gallbladder, and severe pain.

Feasibility of Continuing Biopsies at High Rates

Eventually, we will hopefully be able to understand diagnoses without the need for a biopsy. Clinical trials are currently reliant on pre- and post- biopsies to test the efficacy of the interventions, but once we move away from the overuse of the biopsy, the other technologies will become standard practice because it is so much less invasive.

Advances in Non-Invasive Technologies

Ultrasounds and MRIs are two key non-invasive diagnostics. Questions that need to be asked when determining diagnosis are:

- Are we looking at this qualitatively? Is this good or bad, right or wrong?
- Are we looking at this quantitatively? That is when a doctor looks at the organ, observes abnormalities, and the abnormality has a certain metric.

The three key steps a radiologist follows is:

- to perform the study,
- read the study,
- and determine how the information is used.

Having quantitative data helps aid this process. However, how good are we at finding metrics for diagnosing liver diseases? In short, there are options that provide clarity and guidance for diagnoses, such as ultrasounds (more simple) and MRIs (slightly more complicated). Hopefully, in the near future, the technical function of these tools will place non-invasive diagnostics on the same level as a biopsy.

Interpretation of NIDs

The interpretation of radiology reports has improved over time but there is still room for major improvement and progression. In a perfect world, we could press a button and see the quality of the liver. It is not that simple but we strive for the best and hope for the simplest and least invasive way possible.

Patient Perspective: Scott

“Thanks so much [to] the medical community that’s looking for alternatives, because biopsies right now trigger me.” - Scott Linscott

Scott’s biopsy experience consisted of being told it was not a big deal and it would not hurt. However, the doctors around him seemed nervous which made him nervous. His nurse told him, “Be sure to tell your doctor about your experience today because I can’t say anything,” in response to the pain and discomfort Scott experienced. This fear patients have of having to get another biopsy is reason enough to push for change.

Limitations of Biopsies

Because biopsies only take a limited piece of the liver, the unfortunate reality is that a biopsy could sample a small section of the liver - but a centimeter over could be a completely different disease outcome. Non-invasive diagnostics are a way to alleviate discomfort for patients and mitigate under-diagnosing liver disease.

Technological Advancements

We have made such significant progress in artificial intelligence. There are now ways to categorize the images we take when diagnosing patients and standardize our approach to the stages of diagnoses within the spectrum of NAFLD. This may seem like science fiction but it is more within our reach than it may seem. For example, if you get an abdominal MRE, is there more information to be gained by using technology like AI? There may be undiagnosed conditions that these technologies can find and we can use that to connect with patients and get them the care they need.

Diffusion of Innovation: Access to Non-Invasives in States like Massachusetts

The variability and performance of exams do not differ in standard or success if the MRE is performed in a rural area versus a city like Boston. Additionally, ultrasounds in their basic form, function the same but additional technology can improve the function of the test.

The success of a machine requires some input and skill rather than pressing a button and expecting the same outcome every time. We have to take the technologies we have and improve them to make the results more homogenous and AI will be critical in making this happen. “AI won’t replace radiologists, but radiologists who use AI will replace radiologists who don’t use AI.”

Identifying Patients at Risk

Identifying risk factors and patients at risk for progressive liver disease is crucial in this fight. Diabetes, obesity, and other risk factors can be used when determining a course of treatment and diagnosis for patients.

Next Best Steps

- Standardization of testing and stronger guidelines
- Identifying patients at risk
- Centering patient voices

Appendix D: New York Panel Synopsis

Special Message: US Representative Adriano Espaillat (NY-13)

Scott Friedman, MD - Dean for Therapeutic Discovery and Chief of the Division of Liver Diseases, Icahn School of Medicine at Mount Sinai

Gerard Marinaccio - Liver Transplant Patient and Advocate

U.S. Representative Adriano Espaillat (NY-13) Excerpt

The rate of liver disease leading to liver cancer is a rising cause for concern in global cancer rates. In the midst of COVID-19, we are seeing liver diseases continue to rise and we must remain vigilant when it comes to liver health. We are seeing a concerning mortality rate among patients with chronic liver diseases and programs such as Beyond the Biopsy and GLI Live are opportunities to become informed.

The Discussion

What Is A Liver Biopsy and Why Do We Do Them?

A liver biopsy is a diagnostic tool that utilizes inserting a needle into the liver and extracting a small piece of the liver to determine the level of damage. How the liver biopsy is done is part of the challenge because it is invasive and only captures a small fraction of the liver where there may be critical differences inches apart.

If There Is Another Option, We Should Use It

There are risks associated with biopsies, including severe hemorrhage. Additionally, doctors cannot perform biopsies regularly because they are hard on the patients, but at the moment there are some situations where a biopsy is currently required. The field needs more options. They're out there - they just need to be recognized.

Patient Perspective: Gerard Marinaccio

Completely by chance, Marinaccio attended his yearly physical and his physician ordered extra tests upon seeing his liver levels were concerning. Upon more testing, he was diagnosed with liver disease and got a biopsy. Subsequently, Marinaccio was diagnosed with liver cancer and went on the transplant list. After treatments that left him uneasy, he eventually received a successful transplant.

Famous Last Words: "There's Nothing to Worry About"

Many components of Marinaccio's medical history show that there is a high likelihood many people have liver disease and are undiagnosed. Additionally, the narrative of receiving a biopsy but the experience being brushed off with the patient being told 'It's nothing, don't worry about it' is concerning - especially because it turned out Marinaccio's doctors should have been alarmed and acted on it.

Liver Cancer

Liver cancer is on the rise at alarming rates. This is an indicator of a lack of early diagnosis and recognition that liver diseases that may precede liver cancer. Curative therapies for liver cancers depend on diagnosing it early on, which in many cases has required a biopsy. Marinaccio's story is positive because it underscores the success and importance of transplants but also is a cause for pause because, as Dr. Friedman said, "What if he had known 10 years earlier that he had NASH?"

Alternatives to Liver Biopsies

There are some things we can currently do that stratify the possibility of liver disease. There needs to be a way to view all patient histories and identify risk factors and concurrent conditions, such as high-risk populations with diabetes.

An example of a non-invasive diagnostic is a compilation of blood tests known as the Fib4, which is a way of incorporating lab tests and the patient's age as a way to estimate if a patient has NASH. This method is not concrete enough for specific diagnosis but is a method of scanning large populations and identifying at-risk groups.

We have been dependent on tissue analysis with biopsies and have forgotten about measurements to test the actual function of the liver, which may prove useful. "Blood work is easy, imaging is easy. I definitely prefer that (as opposed to a biopsy)" states Marinaccio.

Access to Non-Invasives and Liver Care as a Whole

There are not enough specialists in the United States for the rate of liver diseases. Equipping primary care physicians with non-invasive education materials and tools is vital. "Use what you have; if you have blood tests, use blood tests. If you have an ultrasound, use an ultrasound. If you have an MRI, use an MRI," Donna Cryer emphasized.

The best way to ensure that, no matter where a patient is, they can take the proper step for their liver health before it's too late is by creating access and utilizing resources we already have across the country and across the globe. Specialization in liver health for doctors has changed over the years. There are unique opportunities now to take an extra year to become familiar with liver health. A majority of patients with liver health issues are seeing a gastroenterologist. When their condition progresses, there needs to be access to doctors with specialization in different liver conditions.

Clinical Trials

One of the many contributions a patient can make is to be enrolled in clinical trials. There is no other way to get the best results because theoretical, computer-based assessments and animal tests are limited. Patients whose conditions are less severe and progressed are an important part of this because the more rapidly that conditions can be identified and treated, the better research can progress. Donna Cryer states that "we need patients to be involved in trials that involve the validation of non-invasive diagnostics."

Representation, diversity, and inclusion play a huge role in the efficacy of clinical trials. Without a broad group of participants, the research is less applicable to communities we see affected by liver diseases. For example, the rate of Hispanics with liver disease is estimated at 19%. This number shows that we need to acknowledge the difference in epigenetics, gene expression, and environmental and ecological differences, and how diseases present in different populations. Additionally, African-Americans have been shown in research to present with liver diseases less, but more research is required.

Another aspect that needs to be explored is the relationship between the microbiome and health outcomes. A focus on research is crucial and the need for patients to be involved in this research is something that cannot be overlooked.

Closing Patient Perspective

“I always tell people, you have to advocate for yourself” states Marinaccio. Patient education and self-efficacy are crucial in the fight for liver health. When patients know more about the conditions they have or they are at risk for, more can be done preventatively. In Marinaccio’s experience, if doctors and people had been talking about NASH earlier, the course of treatment and health outcomes could have been different. Marinaccio’s doctor chose to invest time and extra tests on his health. If all doctors and primary care providers put in this effort it could impact the field of liver health.

Appendix E: The Wrap-Up Synopsis

Presented by: Donna Cryer, CEO, and Founder of the Global Liver Institute

Over the past few weeks, the Global Liver Institute has utilized virtual platforms such as Facebook Live to shine a spotlight on the importance of non-invasive diagnostics in liver diseases and advocating for their adoption in medical practice. By encouraging the use of non-invasive diagnostics and moving away from the biopsy as the “gold standard,” GLI is advocating for a fuller, safer, and less costly experience for patients. A fantastic array of experts, including patients, doctors, and policymakers have offered their time and expertise to advocate for this cause. We have gone coast to coast and everywhere in between for this campaign, with an episode starting with Colorado, moving to Massachusetts, and finally to New York.


At the time this episode was recorded, it was the 26th anniversary of Donna's own liver transplant. As she said, “It has been a long journey that I hope to continue, certainly. But it has been populated from time to time by liver biopsies, which were in some cases painful, in all cases invasive, and something that has impassioned me to make sure we move beyond it.”

Throughout the campaign, topics such as the different types of non-invasive diagnostics, the importance of research, and cross-specialty, multidisciplinary care have been discussed. All of these topics are applicable to liver health and we can use these conversations to advocate for patients.

We can and we must move beyond the liver biopsy. It is unethical to administer an invasive test that we cannot interpret and has the number of limitations that it has. When science and technology are evolving so quickly, it is unacceptable to continue to use liver biopsies instead of holistic and non-invasive options. Non-invasive diagnostics cover a wide range of generalized tests including blood tests (Fib4, the NAFLD score) and imaging tests (ultrasounds, MRI, MRE, LiverMultiScan, FibroScan).

It is important to recognize the access and identification of non-invasive diagnostics in areas that are not in close proximity to an educational institution or hospital, domestically, and globally. When we discuss the importance of non-invasive diagnostics, risk factors, family history, and resources that we already possess, such as blood tests, the case for “biopsies as the gold standard” loses its feasibility. The case to move beyond the biopsy wants to leave you with greater knowledge about tools that are available to you or your clinicians to identify if you have NAFLD or NASH. The value of non-invasive diagnostics cannot be overstated and the options are growing by the day. Patient participation in clinical trials is crucial with diversity and inclusion at the center of these conversations. People of color and an array of cultural backgrounds is particularly important for clinical trials so that research is representative of the communities that liver disease impacts.

If you missed any of our episodes, they are available on the Global Liver Institute website and Facebook page. If you cannot get around to watching these episodes, however, know that the ultimate goal of this campaign is to recognize that there are options beyond the biopsy and the safety and comfort of patients are at the forefront of this discussion.



Beyond
the Biopsy

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